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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/027,439	02/20/98	PORTUGAL F	044198.0000

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EXAMINER	
SOUAYA, J	
ART UNIT	**PAPER NUMBER**
1655	16

DATE MAILED: 12/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/027,439	Portugal et al
Examiner	**Group Art Unit**
Jehanne Souaya	1655

☒ Responsive to communication(s) filed on *Oct 3, 2000* .

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *21-44* is/are pending in the application.

Of the above, claim(s) *21-36* is/are withdrawn from consideration.

☐ Claim(s) _____ *is/are allowed.*

☒ Claim(s) *37-44* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ *are subject to restriction or election requirement.*

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ *is/are objected to by the Examiner.*

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *15*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Currently, claims 37-44 are pending. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections not reiterated are hereby withdrawn. The following rejections are either newly applied or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

3. Newly added claims 43 and 44 (subjected matter of canceled claim 20) as rejected under 35 U.S.C. 102(a) as being anticipated by Cilia et al (Mol. Biol. Evol., vol. 13, pp 451-461, 1996).

The claims are drawn to nucleic acid molecules having the nucleic acid sequence of SEQ ID NOS 9-12, 14, and 16-21 which are taught by Cilia et al.

Response to Arguments

The term "having" is considered open language, and therefore, sequences having a nucleotide sequence of the claimed SEQ ID NOS are interpreted to mean that these sequences can have additional nucleotides on either side. These sequences are taught by Cilia et al.

Claim Rejections - 35 USC § 103

4. Claims 37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cilia et al or Hogan et al (US patent 5,714,321, 102(e) date is 2/24/94) in view of Faruque et al (J. Clinical Microbiology, 1992, vol. 30, pp 2996-2999).

The claims are drawn to nucleotide sequences of 10-40 nucleotides that comprise regions of the 16s ribosomal RNA or DNA sequences of Shigella species and E. Coli, wherein these sequences are capable of distinguishing Shigella from E.coli. Cilia et al teaches sequence heterogeneities among 16s RNA sequences of E. Coli and Shigella (see abstract, and figure 3) and teaches nucleotide differences among Eubacteria by showing a line up of regions from 16s genes across species levels, showing the nucleotide sequence similarities and differences. Hogan also teaches a method for preparing probes for use in qualitative and quantitative assays wherein the probes are capable of detecting and differentiating between eubacteria (see abstract). Hogan also teaches the hybridization of E. Coli probes to closely related organisms such as Shigella boydii, Sh. flexneri, Sh. dysenteriae, and Sh. sonnei (see col. 52, table 54). Faruque teaches studying

restriction endonuclease restriction patters of rRNA genes to distinguish between different strains of sh. Flexneri. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to construct the DNA sequences of the claimed invention for the use of probes and primers that could distinguish Shigella from E. Coli. Methods of distinguishing between different eubacteria using probes and primers that target regions of similarity and differences was readily known in the art at the time of the invention and is exemplified by the Hogan patent. The ordinary artisan would have been motivated to construct probes and primers of the claimed invention to identify and differentiate E.coli from Shigella as Cilia teaches how closely related the two genus of bacteria are (see Fig 1) and Faruque teaches that closely related sequences from strains of the same bacteria can be used to differentiate the different strains. As the sequences of the 16s rRNA and rDNA sequences of the shigella species and E.coli sequences were known at the time of the invention, it would have been obvious for the ordinary artisan to construct probes and primers to regions of variability to be able to differentiate the closely related bacteria. Such methods were readily known in the art as is shown by the large amount of literature available in the art that identifies regions of variability among closely related bacteria for the purpose of constructing probes and primers useful in methods of differentiation.

Response to Arguments

5. Applicants traverse that non obviousness is determined by application of both factual inquiries and secondary considerations and that factual inquires include scope and content of the

prior art and the difference between prior art and the claims. Applicants traverse that the cited reference do not render the invention obvious. This argument has been thoroughly reviewed but was found non persuasive, because as exemplified by the teachings of the cited references, the state of the art in constructing probes and primers to differentiate closely related organisms was very high at the time the invention was made. Applicant's further traverse that difference exist between the prior art and the claimed invention, for example Cilia does not teach that the T between position 88 and 89 is identifying. Applicant's further traverse that the references don't specifically claim other polymorphisms of the claimed invention. This argument has been thoroughly reviewed but was found unpersuasive. As was discussed previously, the state of the art with regard to constructing probes and primers to differentiate closely related organisms was extremely high at the time the invention was made. One of ordinary skill in the art would have been taught by both Cilia and Hogen and Faruque that one could sequence rRNA and rDNA sequences from closely related species, find regions of similarity and differences (Cilia provides the ordinary artisan with the reasonable expectation of success that such differences exist) in the sequence alignments, and construct probes and primers to these regions to differentiate the organisms. As such methods were already taught in the art at the time the invention was made to be successful, one of ordinary skill in the art would have had a reasonable expectation of success that such probes and primers could be constructed and would differentiate closely related organisms.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. No claims are allowable.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Thursday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya
Patent examiner
Dec. 18, 2000

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600